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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,346	04/30/2001	George Jackowski	2132.013	3157

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MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS, FL 33410

EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,346	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 36-43* is/are pending in the application.

4a) Of the above claim(s) *1 and 41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 36-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and arguments filed August 15, 2005 is acknowledged and has been entered. The specification has been amended as Applicant submitted. Claims 36 and 37 have been amended. Claims 1 and 41-43 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1 and 36-43 are pending. Claims 36-40 are under examination.

Withdrawn Rejections

2. In light of Applicant's amendment, the rejection of claims 36-40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby, withdrawn.

3. All rejections not reiterated herein have been withdrawn.

New Grounds of Rejection

Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 36-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *In re Wands, 858 F .2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*, enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The nature of the invention- the invention is directed to a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 in a patient sample... wherein the presence the biopolymer marker having SEQ ID NO. 1 and a molecular weight of about 1998 daltons is indicative of Type II diabetes. The method is performed by obtaining a sample from a patient, conducting mass spectrometric analysis on the sample, and comparing the mass spectrum profile of the sample with the mass spectrum profile of a biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons in a control sample, wherein the presence of a biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons in the patient sample provides an indication of Type II diabetes.

The state of the prior art- the prior art of record fails to disclose a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons in a patient sample, wherein the presence of the biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons, is indicative of Type II diabetes.

The predictability or lack thereof in the art- there is no predictability based on the instant specification that the claimed method which shows determination of the presence of a biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons, provides and supports an indication of Type II diabetes.

The amount of direction or guidance present- the specification fails to provide adequate guidance to enable the use of a biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons, so as to be indicative of Type II diabetes.

The presence or absence of working examples- there are no working examples that show data and results wherein determination of the presence of a biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons, specifically supports an indication of Type II diabetes. Figure 2 displays a characteristic mass spectrum profile which peaks at 1998 daltons; however, nowhere in the specification provides data that shows that there is a nexus that relates the biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons, with specific indication of Type II diabetes.

The quantity of experimentation necessary- it would require undue amount of experimentation for the skilled artisan to make and use the method as claimed based on the instant specification.

The relative skill of those in the art-the level of skill in the art is high.

The breadth of the claims- as recited, the instant claims are directed to a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 in a patient sample... wherein the presence of the biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons is indicative of Type II diabetes. The method is performed by obtaining a sample from a patient, conducting mass spectrometric analysis on the sample, and comparing the mass spectrum profile of the sample with the mass spectrum of a biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons in a control sample, wherein the presence of a biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons in the patient sample, provides an indication of a Type II diabetes.

Applicant generally discusses SELDI-MS and time-of-flight (TOF) detection procedures which are used to maximize the diversity of biopolymers which are verifiable within a particular sample for analysis of their ability to enable diagnosis of a disease state relative to the presence or absence of the biopolymer marker in page 12, lines 1-17 of the specification. Pages 12-16 of the specification provides numerous biopolymer markers associated with diseases of the complement system, i.e. the major effector of the humoral branch of the immune system (C3 deficiency- recurrent bacterial infection and autoimmune reactions, etc.), and the Syndrome X continuum, i.e. multifaceted

syndrome (insulin resistance/hyperinsulinemia, dyslipidemia, hypertension, obesity, glucose intolerance, non-insulin dependent diabetes mellitus, etc). The specification at page 27, line 17 to page 28, line 2, states that SEQ ID NO. 1 having a molecular weight of about 1998 daltons, is found in serum samples of patients suffering from various diseases including Type II diabetes. Applicant points to Figure 1 and notes that from the data set forth therein, one can conclusively deduce that the marker which is SEQ ID NO. 1, provides indication of an individual suffering from Type II diabetes. However, the specification does not provided data supporting the assertion that a marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons, provides specific indication of Type II Diabetes in a subject. Data provided in Figure 1 is also not convincing because it does not show how the marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons, would have conclusively become a biopolymer marker of Type II diabetes based on its manifestation in relation to the characterization of the disease. The specification at page 26, line 20 provides that serum samples from patients suffering from a variety of disease states were analyzed using one or more protein chips and the profiles were analyzed to discern notable sequences which were deemed in some way evidentiary of at least one disease. The specification states that serum samples were centrifuged, their filtrate was discarded; the retained solution containing two peptides, were analyzed by tandem mass spectrometry to deduce their amino acid sequences. As a result of these procedures, the disease specific marker consisting of SEQ ID NO. 1 was found.

To this end, it is unclear how SEQ ID NO. 1, having a molecular weight of 1998 daltons, was identified as a "notable sequence" or how it is deemed evidentiary as

providing diagnosis of a disease state, much less, a specific one such as Type II diabetes. Nowhere in the disclosed procedure provides why and how the notable sequence is chosen amongst all other proteins and peptides present in the samples. Specifically, there is no nexus established between samples of patients having different disease states, identification of SEQ ID NO. 1 having a molecular weight of 1998 daltons as a disease marker, and determining that the SEQ ID No. 1 having a molecular weight of 1998 daltons is a diagnostic marker indicative of Type II diabetes.

The specification specifically lacks guidance to enable one skilled in the art to determine the incidence of Type II Diabetes as related to the presence or absence of a biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons. The specification further lacks adequate guidance to enable one skilled in the art to distinguish between any and all disease states disclosed in the specification, including Type II Diabetes.

According to Strongin (Sensitivity, Specificity, and Predictive Value of Diagnostic Tests: Definitions and Clinical Applications, Laboratory Diagnosis of Viral Infections, Lennette, E., ed., Marcel Dekker Inc., New York, pages 211-219 (1993)), a number of characteristics need to be considered in the development of any suitable diagnostic assay. These characteristics include the following: 1) sensitivity of the assay, 2) true-positive test rate, 3) false-negative test rate, 4) specificity, 5) false-positive test rate, 6) true-negative test rate, 7) predictive value, 8) prevalence, 9) efficiency, and 10) accuracy of the diagnostic assay. Additional considerations are also examined to enable the clinician to practice the invention including specific assessment of 1)

maximum sensitivity desired, 2) maximum specificity desired, 3) maximum efficiency desired, 4) how sensitivity or specificity is maximized, and 5) how predictive value is maximized. An essential understanding of these factors is required to enable a skilled artisan to accurately use and interpret any given diagnostic test. Since the specification lacks any teaching of how the diagnostic tests were performed, including information regarding the patients from which the samples were obtained, and whether any consideration was given to the characteristics aforementioned, it would require undue consideration for one skilled in the art to make and use the invention as claimed.

Because of the lack of description in the specification for the claimed method, it cannot be conclusively determined from the data presented in Figure 1 that anyone or everyone who has the biopolymer marker suffers from any disease, including specifically Type II Diabetes. Patent protection is granted in return for enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1996), stating in context of the utility requirement that "a patent is not a hunting license. It is not a reward for the search, but for compensation for its successful conclusion." Tossing out the mere germ of an idea does not constitute an enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by the inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Genentech Inc. v. Novo Nordisk A/A (CAFC) 42 USPQ2d 1001. That requirement has not been met in the instant disclosure with respect to the method of providing indication of Type II

Diabetes, by detecting a biopolymer marker in a patient sample and comparing the detected biopolymer to a biopolymer marker having SEQ ID NO. 1 and having a molecular weight of 1998 daltons.

In view of the teachings of In re Wands, 8 USPQ2d 1400, it has been determined that the level of experimentation required to enable the breadth of the claims is undue. It has been set forth above that 1) the experimentation required to enable an indication of Type II diabetes using the biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons, would be great as 2) there is no experimental evidence provided that would indicate that the claimed method would work to provide indication of Type II diabetes, using the biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons; 3) there is no adequate guidance that shows that the claimed method can be used to exclusively provide indication of Type II Diabetes using the biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons that is identified from the patient sample, 4) the nature of the invention is a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 in a patient sample... wherein the presence the biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons is indicative of Type II diabetes; the method is performed by obtaining a sample from a patient, conducting mass spectrometric analysis on the sample, and comparing the mass spectrum profile of the sample with the mass spectrum profile of an biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons in a control sample, wherein the presence a biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons in the patient sample, provides an indication of Type II

diabetes, 5) the relative skill of those in the art is high, yet 6) the state of the prior art has been shown to be unpredictable as evidenced by the fact that no prior art has been cited that shows the claimed biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons, provides specific indication of Type II diabetes, and lastly 7) the claims broadly recite a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 in a patient sample... wherein the presence the biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons is indicative of Type II diabetes; the method is performed by obtaining a sample from a patient, conducting mass spectrometric analysis on the sample, and comparing the mass spectrum profile of the sample with the mass spectrum profile of a biopolymer marker having SEQ ID NO: 1 and a molecular weight of 1998 daltons in a control sample, wherein the presence a biopolymer marker having SEQ ID NO. 1 and a molecular weight of 1998 daltons in the patient sample, provides an indication of Type II diabetes.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 36-40 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-6 of U.S. Patent No. 6,756,476. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 which is SSKITHRIHWESASLLR, wherein mass spectrometric analysis is performed on a patient sample to determine the presence of a biopolymer marker having SEQ ID NO. 1, and wherein a confirmed presence of the biopolymer marker having SEQ ID NO. 1 provides an indication of Type II diabetes.

Prior US Patent No. 6,756,476 is silent in teaching that SEQ ID NO. 1 has a molecular weight of 1998 daltons. However, as US 6,756,476 provides that SEQ ID No. 1 has substantially the same sequence which is SSKITHRIHWESASLLR as the claimed invention, it is deemed that the biopolymer marker having SEQ ID NO. 1 taught in US 6,756,476 which is rendered to be diagnostic of Type II diabetes, is the same biopolymer marker having SEQ ID NO. 1 and having a molecular weight of 1998 daltons, used to provide an indication of Type II diabetes, as that in the claimed invention.

6. Claims 36-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-40 of copending Application No. 09/845,736. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a method for determining the presence of a biopolymer marker having SEQ ID NO. 1 which is SSKITHRIHWESASLLR, wherein mass spectrometric analysis is performed on a patient sample to determine the presence of a biopolymer marker having SEQ ID NO. 1, and wherein a confirmed presence of the biopolymer marker having SEQ ID No. 1 provides the presence of a disease.

ASN 09/845,736 is silent in teaching that SEQ ID NO. 1 has a molecular weight of 1998 daltons and that SEQ ID NO. 1 provides indication of Type II diabetes. However, although the instant claims are drawn to the identification of Type II diabetes and the claims in '736 are drawn to the identification of congestive heart failure, they are not seen to be different since the specification for both applications provides the same SEQ ID No. 1 which is SSKITHRIHWESASLLR, and asserts that SEQ ID NO. 1 relates to both congestive heart failure and Type II diabetes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

7. Applicant's arguments filed August 8, 2005 have been fully considered but they are not persuasive.

A) Applicant uses Patterson to support his contention that the method described by Weinberger is analogous to the instant specification and that the same approach to interpretation was used by the instant inventors to identify seminogelin fragments as potential markers to distinguish between benign prostate hyperplasia and prostate cancer, based on differential expression of the fragments.

In response, Patterson's teaching with regards to the method described by Weinberger, which is deemed to be analogous to the instant specification provides the known and characterized protein, i.e. seminogelin fragments, as *potential differential markers* between two specific diseases. Therefore, the teaching of Patterson is not analogous or commensurate in scope to Applicant's claim to SEQ ID NO. 1 as being a *diagnostic marker indicative of Type II diabetes* if present, amongst all other proteins found in a patient sample.

B) Applicant argues that those skill in the art are both highly knowledgeable and skilled and it is obvious that no undue experimentation is required for a skilled artisan to follow any of the chromatographic and mass spectrometric protocols presented in the instant specification in order to use the claimed invention. Applicant contends that mass spectrometric profiles can be used as reference points for identification of proteins present in an unknown sample and a skilled artisan will be able to ascertain the presence and identity of the peptide, i.e. SEQ ID NO.1 by comparison with mass spectrometric profiles.

In response, Applicant's argument is not on point since the issue is not whether the skilled artisan can perform chromatographic and mass spectrometric protocols to identify specific proteins from a mass spectrometric profile, but the issue is whether the skilled artisan would readily conclude that a specific protein identified would provide specific diagnosis of a disease such as Type II diabetes, upon identification of its amino acid sequence, i.e. SEQ ID NO. 1, and molecular weight of 1998 daltons, given Applicant's limited disclosure and guidance of how SEQ ID NO. 1 is determined to be indicative of Type II diabetes in a subject.

C) Applicant argues that Capiaumont et al. as cited by Examiner also use small groups with small numbers of participants, which is similar to numbers used in Applicant's limited assay pool, in concluding that the HWESAS marker could be a marker of renal function. As such and in the same manner as Capiaumont, Applicant contends that their finding of differential expression of SEQ ID NO. 1 in Type II diabetes patients versus healthy patients, provides that SEQ ID NO. 1 *could be* a marker for Type II diabetes.

In response, Capiaumont's teaching which is deemed to use similar numbers of assay pool as the instant specification provides that the HWESAS protein, *has a potential role in or relationship with* renal function and does not claim to using SEQ ID NO. 1 as a *diagnostic marker providing indication* of renal disease, which is chosen amongst all other proteins found in the patient sample. Accordingly, Applicant's argument with regards to Capiaumont's findings, is not commensurate in scope with the

subject matter that is being claimed, i.e. SEQ ID NO 1 as a diagnostic marker indicative of Type II Diabetes.

Response to Declaration

8. Applicant provides a Declaration under 37 CFR 132 to support that Appendix A was originally filed in Applicant's ASN 09/846,330, which is now US 2002/0160420. According to Applicant, the data from a clinical trial involving over 500 patients, clarifies the identification of SEQ ID NO. 1 in serum samples of patients suffering from a variety of disease states as being evidentiary of Type II diabetes.

In response, Appendix A does not appear to have provided evidentiary showing that a population of previously unknown subjects can be specifically identified as having an indication of Type II diabetes using the claimed method and biopolymer marker having SEQ ID NO. 1, which is recited in the rejected claims. Appendix A shows a list of 500 patients suffering from a variety of diseases such as stroke, congestive heart failure, myocardial infarction, and Type II diabetes and individually lists the protein names, sequences, and molecular weights of the different biopolymer markers that are manifested by them. However, Appendix A and Figure 1 still fail to establish how Applicant arrived to the relevancy of the biopolymer marker having SEQ ID NO. 1 and molecular weight of 1998 daltons to an indication of Type II diabetes, as opposed to the numerous other diseases. Again, Applicant has not presented how a such a nexus would have been established between the positive identification of the claimed protein, its molecular weight, and the alleged incidence of Type II diabetes in a patient.

Additionally, prior art (Capiaumont et al.) shows that the claimed biopolymer marker is also exhibited in patients having chronic renal failure. Accordingly, based on Applicant's disclosure, data, and arguments, a patient having chronic renal failure, albeit asymptomatic of Type II Diabetes, would potentially be diagnosed with Type II Diabetes, on the basis of "differentially expressed peptides" upon which SEQ ID NO. 1, having a molecular weight of 1998 is manifested.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday from 7:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
October 29, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
10/31/05